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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,771	10/27/2005	Paul Stroobant	50189/003002 4907	
21559 CLARK & FI	1559 7590 01/15/2008 CLARK & ELBING LLP		EXAMINER	
101 FEDERAL	L STREET		LUNDGREN, JEFFREY S	
BOSTON, MA 02110		,	ART UNIT	PAPER NUMBER
			1639	
			NOTIFICATION DATE	DELIVERY MODE
			01/15/2008	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

<del></del>	Application No.	Applicant(s)				
	10/518,771	STROOBANT ET AL.				
Office Action Summary	Examiner	Art Unit				
	Jeff Lundgren	1639				
The MAILING DATE of this communication app						
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION  36(a). In no event, however, may a reply be to the state of the state	NN. imely filed  m the mailing date of this communication. IED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on	<u>.</u>					
2a) This action is <b>FINAL</b> . 2b) This	☐ This action is <b>FINAL</b> . 2b)☐ This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-52</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) 1-52 are subject to restriction and/or election requirement.						
Application Papers		•				
9) The specification is objected to by the Examine	r.					
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Offic	e Action or form P1O-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Paper No(s)/Mail Date.						
3) Information Disclosure Statement(s) (PTO/SB/08)  5) Notice of Informal Patent Application						
Paper No(s)/Mail Date 6) Other:						

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#### DETAILED ACTION

#### Election/Restrictions

This application contains claims directed to the following patentably distinct sets of species:

- A. The first and second biological samples (e.g., claims 29-37);
- B. The analytical method for comparing (e.g., claims 48 and 49); and
- C. The difference in the relative abundance (e.g., claims 51 and 52).

PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

Here, the claimed biological samples, do not all have a common property or activity, and possess different biological structures. The analytical methods of NMR and mass spectrometry are unrelated alternatives to one another. And the determination point in the difference of the relative abundance of the samples is also unrelated between species.

Accordingly, restriction to a single species as defined above is proper.

Applicants are advised that a reply to this requirement must include an identification of the species for each set that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141. If claims are added after

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the election, Applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that in order for the reply to this requirement to be complete, the reply must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.43). Because the above restriction/election requirement is complex, a telephone call to Applicant to request an oral election was not made. See MPEP § 812.01.

## Time for Reply

Applicant is reminded that 1-month (not less than 30 days) shortened statutory period will be set for reply when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program. M.P.E.P. § 809.02(a).

### Correction of Inventorship

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Conclusions**

If Applicants should amendment the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and

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provide any statements that might help to identify support for the claimed invention (e.g., if the amendment is not supported *in ipsis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Schultz, can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**JSL** 

/Jon D. Epperson/ Primary Examiner, AU 1639